REMARKS

I. Status of the Claims

Claims 1, 5-6, and 11-13 are pending.

II. Rejection Under 35 USC 112, first paragraph

Claims 1, 5 and 6 stand rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses this rejection.

As set forth in MPEP 2163.02, the standard for determining compliance with the written description requirement is as follows:

> Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

The specification as originally filed provides full written description support for pending claims 1, 5, 6, and 11-13. Applicant's claimed invention is directed to methods consisting of the administration of atorvastatin or a pharmaceutically acceptable salt thereof in an amount effective to cause an aggressive lowering of LDL cholesterol such that catheter-based revascularization is either prevented or delayed in patients suffering from coronary artery disease and in need of such treatment. Example 1 illustrates with reasonable clarity that Applicant had possession of the claimed invention as of the filing date.

Example 1 describes "...a multi-center, open-label, clinical trial involving 341 patients. [The] trial is intended to determine whether aggressive lipid lowering with [atorvastatin] can

significantly delay or even obviate the need for catheter-based revascularization in patients diagnosed with coronary artery disease." Specification, page 7, lines 12-16. The 341 patients are "...patients who have just undergone or are about to undergo angiography and in whom a recanalization procedure is recommended." Specification, page 8, lines 16-18. The 341 qualified patients were subject to the same inclusion as well as exclusion criteria and then randomized into two (2) treatment groups. Group 1 received atorvastatin while Group 2 underwent a recanalization procedure followed by usual care. Specification, page 8, lines 1-13. The purpose of the study was to compare aggressive lipid lowering with atorvastatin versus revascularization treatments/recanalization procedure followed by usual care. Specification, page 7, lines 18-22 and page 12, lines 3-5. The results of the study are set forth on page 25, lines 11-25 of the Specification:

> The atorvastatin-treated patients had their LDL cholesterol reduced on average to 77 mg/dL from 140 mg/dL before treatment. That is well below the 130 mg/dL level considered as the target for people without heart disease, and the 100 mg/dL threshold for patients with symptoms of heart disease. LDL cholesterol in patients treated with angioplasty fell to about 119 mg/dL during the study. This study clearly establishes that LDL levels well below the 100 mg/dL goal is unexpectedly better and to be preferred. The results establish that aggressively lowering LDL by administering an effective amount of a cholesterol lowering agent [in this instance, atorvastatin] will enable patients to forego costly angioplasty without fear of increasing their risk of heart attack. The data establish that 87% of patients randomized to atorvastatin treatment, who were originally candidates for angioplasty, were instead able to remain on drug therapy alone for the duration of the 18-month trial, without experiencing any adverse cardiovascular events.

The Examiner points to page 10, line 12; page 16, line 4; and page 17, line 17 of the Specification to support the assertion that "...modifications to diet, supplemental drugs, and reducing alcohol intake are included in applicant's disclosed method." Applicant respectfully disagrees since such criteria are not relevant to Applicant's invention since such criteria were

applied to patients of both Group 1 and Group 2, and thus would not hinder the purpose of the study: to compare the ability of atorvastatin against recanalization procedure followed by usual care to aggressively lower lipid levels. *See* Norian Corp. v Stryker Corp., 70 USPQ2d 1508 (2004). As set forth above, the results indicate that compared to a recanalization procedure followed by usual care, administration of atorvastatin was unexpectedly better in aggressively lowering LDL cholesterol levels.

For the reason set forth above, the Specification as originally filed would convey with reasonable clarity to one of skill in that art that Applicant was in possession of the claimed invention. As such, the Written Description requirement is fully met. Applicant respectfully requests this rejection be withdrawn.

III. Rejection Under 35 USC 102

Claims 1, 5, 6 and 11-13 stand rejected under 35 USC 102(b) as being anticipated by Bocan, WO 97/16184. Applicant respectfully traverses this rejection.

As set forth in MPEP 2131, in order to anticipate a claim, the reference must teach every element of the claim. Bocan fails to do so.

Applicant's claimed invention is directed to a method consisting of administering atorvastatin or a pharmaceutically acceptable salt thereof in an amount effective to cause an aggressive lowering of LDL cholesterol by at least forty percent from baseline or by about fifty percent or more from baseline for the prevention or delay of catheter-based revascularization in patients suffering from coronary artery disease in need of such treatment.

Bocan is directed to a method for regulating lipid concentration by administration of a combination of two compounds; in this instance, (a) an ACAT inhibitor and (b) a HMG-CoA reductase inhibitor (e.g. atorvastatin). *See* Abstract and Summary of the Invention on page 2 of Bocan. Thus the method of Bocan relies upon the administration of a combination of at least two compounds (a) and (b). Further, Bocan teaches that the combination of an ACAT inhibitor

and a HMG-CoA reductase inhibitor results in greater reduction in plasma VLDL and LDL cholesterol and increases HDL cholesterol than either alone. *See*, for example, Abstract. Thus based on the teachings of Bocan, one of skill in the art would administer the combination of (a) the ACAT inhibitor and (b) HMG CoA reductase inhibitor rather than either of (a) or (b) alone.

Applicant's claimed methods do not rely on a specific combination of compounds but rather the administration of atorvastatin or a pharmaceutically acceptable salt thereof alone to unexpectedly cause an aggressive lowering of LDL baseline such that catheter-based revascularization or recanalization procedures can either be prevented or delayed in patients suffering from coronary artery disease and in need of such treatment. Bocan fails to teach or suggest all elements of Applicant's claimed invention. Thus, Applicant's claimed invention is not anticipated by Bocan. Applicant respectfully requests this rejection be withdrawn.

IV. Conclusion

Applicant respectfully requests reconsideration of the subject application in view of the above amendment and remarks. The subject application is now in condition for allowance and early notice to that effect is respectfully solicited.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 23-0455. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,

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